

Food and Drug Administration Rockville MD 20857

SEP 20 1999

1 6 2 2 '90 SEP 21 P1 :46

The Honorable John J. Duncan, Jr. House of Representatives Washington, D.C. 20515-4202

Dear Mr. Duncan:

Thank you for your letter of July 9, 1999, on behalf of your constituent, Dr. Timothy Johnson of Knoxville, Tennessee, concerning actions by the Food and Drug Administration (FDA or the Agency) in regard to labeling of foods treated with ionizing radiation.

The 1997 FDA Modernization Act (PL 105-115) states that "[n]o provision . . . shall be construed to require on the label or labeling of a food a separate radiation disclosure statement that is more prominent than the declaration of ingredients . . ." FDA published a final rule implementing this provision of the law in the <a href="Federal Register">Federal Register</a> of August 17, 1998. A copy of this regulation, along with the pre-existing labeling requirements for food treated with ionizing radiation, Title 21 <a href="Code of Federal Regulations">Code of Federal Regulations</a>, § 179, is enclosed for your information.

In addition, the Statement of Managers accompanying the FDA Modernization Act directed FDA to publish for public comment further proposed changes to the Agency's current labeling regulations. The managers stated their intention that any required labeling be of a type and character such that it would not be perceived to be a warning or give rise to inappropriate consumer anxiety. On February 17, 1999, FDA published an Advance Notice of Proposed Rulemaking (ANPR) in the Federal Register soliciting public comment on whether additional revisions to the current irradiation labeling requirements are needed and, if so, what form such revisions might take. The deadline for comments in response to the ANPR was extended to July 19, 1999.

We have forwarded Dr. Johnson's correspondence to the Docket for inclusion in the record. FDA's final approach to labeling

9811-1038

C 4745 / ANS

Page 2 - The Honorable John J. Duncan, Jr.

of irradiated foods will take into account all of the data and information received.

Because your constituent may be concerned about irradiation labeling for meat and poultry, you may also wish to contact the United States Department of Agriculture (USDA) for information. (USDA has primary regulatory authority over meat and poultry products, including the labeling of such products.)

We have also enclosed some general background on the issue of irradiation. We trust this information responds to your concerns. If you have further questions about this or any other matter, please do not hesitate to contact us again.

Sincerely,

Jane J. Kurly Melinda K. Plaisier

Melinda K. Plaisier
Interim Associate Commissioner
for Legislation

Enclosures

cc: Dockets Management Branch (98N-1038)

JOHN J. DUNCAN, JR. 2D DISTRICT, TENNESSEE

2400 RAYBURN HOUSE OFFICE BUILDING WASHINGTON, DC 20515–4202 PHONE: (202) 225–5435 FAX: (202) 225–6440

> 800 MARKET STREET SUITE 110 KNOXVILLE, TN 37902 PHONE: (423) 523-3772 FAX: (423) 544-0728

262 E. BROADWAY MARYVILLE, TN 37804-5782 PHONE: (423) 984-5464 FAX: (423) 984-0521

6 E. MADISON AVENUE COURTHOUSE ATHENS, TN 37303-4297 PHONE: (423) 745-4671 FAX: (423) 745-6025

## Congress of the United States

House of Representatives Washington, DC 20515-4202

July 9, 1999

COMMITTEES.

TRANSPORTATION AND INFRASTRUCTURE

SUBCOMMITTEES:

AVIATION—CHAIRMAN PUBLIC BUILDINGS AND ECONOMIC DEVELOPMENT

RESOURCES
SUBCOMMITTEES:
NATIONAL PARKS, FORESTS AND LANDS
ENERGY AND MINERAL
RESOURCES

E-MAIL: jjduncan@mail.house.gov

Home Page HTTP://www.house.gov/duncan/

Dr. Michael Friedman Commissioner Food and Drug Administration 5600 Fishers Lane Rockville, Maryland 20852-1750

Dear Dr. Friedman:

I was recently contacted by Timothy Johnson, a member of my constituency. Mr. Johnson is concerned about possible changes in the labeling rules governing irradiated food products.

Enclosed please find a copy of his letter expressing his thoughts about this matter. I am sure he would appreciate your careful consideration of any new regulations which ease current requirements.

Thank you for your time and attention. If I can be of any possible assistance, please do not hesitate to let me know.

With kindest regards, I am

Sincerely,

OHN J. DUNCAN, JR ember of Congress

JJD:jm

Enclosure

No. 99-4694

Subject: Irradiation Labeling

Date: Tue, 22 Jun 1999 21:38:02 -0700

From: "Dr. Tim Johnson N.D." <drherb@icx.neb

Organization: Herbs and More

To: Congressman, Jimmy, Duncan

Date: 6/22/99

Congressman Duncan 800 Market Street Suite 110 Knoxville, TN 37902

Re: Docket # 98N-1038, "Irradiation in the Production, Processing, and Handling of Food"

Dear Congressman Duncan

The FDA should retain the current labeling law, the current terminology of "treated with radiation" or "treated by irradiation," and the use of the radura symbol on all irradiated whole foods. Regarding the issue of labeling, in its initial petition, the FDA concluded that irradiation was a "material fact" about the processing of a food, and thus should be disclosed. The material fact remains; therefore, labeling should remain.

Consumer acceptability, storage qualities and nutrients are affected. Some irradiated foods have different texture and spoilage characteristics than untreated foods. Most fruits and vegetables have nutrient losses that are not obvious or expected by the consumer. In addition, processing by irradiation causes chemical changes that are not evident and are potentially hazardous. Meat may have a higher level of carcinogenic benzene. All irradiated foods contain unique radiolytic products that have never been tested. Whether or not the FDA has approved irradiation as safe, it remains a new technology with no long-term human feeding studies.

Consumers certainly have a right to know if this process has been used on their food. As to the kind of label used, I believe that label should be large enough to be readily visible to the consumer, on the front of the package. The label contains important information regarding the processing of the contents. For displayed whole foods such as produce, a prominent informational display similar to that used for meats should be used (but containing the term "irradiation" and the radura).

Because of the newness of the technology and the need to assess the public health effects of widespread use of irradiated foods, I believe that the FDA's labeling requirement should not be permitted to expire.

Yours truly,

Dr. Timothy Johnson N.D. Knoxville, TN 37921

22505

98N-1038

C 4745